



November 18, 2016

Dr. David Widawsky
Director, Chemistry, Economics and Sustainable Strategies Division
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460-0001

Re: Input of the American Chemistry Council on the Inventory Reset Process

Dear Dr. Widawsky:

The American Chemistry Council (ACC) offers several considerations to the U.S. Environmental Protection Agency (EPA) as the agency prepares its proposed “Inventory Reset”¹ Rule under Section 8(b)(4) of the Toxic Substances Control Act (TSCA) as required by the Lautenberg Chemical Safety Act (LCSEA).

We strongly support EPA’s vision of a simple and efficient reset process. The process should minimize the burden on both manufacturers subject to the notification obligation as well as the agency, and allow an opportunity for corrections before the reset process has been completed. It should effect its fundamental purpose – to designate chemicals as either active or inactive in advance of prioritization. It should also set out a future mechanism so that inactive chemicals can be designated as active in a quick and turnkey manner.

For chemicals on the Public Inventory, EPA should not require multiple “active” notifications, from multiple companies, for the same chemical. This magnifies cost and paperwork for no reason. EPA can avoid this unnecessary burden by simply acknowledging that it has already received notice of active chemicals in commerce through other program notifications; for example, from the 2012 and 2016 CDR cycles.

Brief observations follow.

The Reset Should Use Current Data about Chemicals in Commerce as the Foundation for the Process, Avoiding Duplication of Notices.

EPA already has recent confirmation of the “active” status of a substantial number of chemicals from a number of regulatory reporting processes, including TSCA Sections 5, 8(a), and 12(b). For example, manufacturers have just completed their most recent Chemical Data Reporting submissions as of October 31, 2016, and all chemicals included in the 2016 CDR (and the 2012

¹ The statute classifies chemicals on the existing Inventory. It neither adds chemicals to the Inventory nor deletes them. While we think this is clear, the public may benefit from some additional clarification in the preamble.



CDR) are by definition active substances in commerce. An efficient reset would take this into account and treat these chemicals as notified to be in active commerce. Similarly, EPA should treat CBI claims for specific chemical identity made in the 2012 and 2016 CDR submission periods, or in other reporting programs, to constitute LCSA-compliant notice of such claims under (4)(B)(ii).

Based upon existing information, EPA could compile a list of substances known to the agency to be active. After comment to confirm the accuracy of the active list, for which comments serve as general notification of their active nature, EPA should publish the remainder of the Inventory as the “inactive” Inventory subject to notification provisions. Such an approach would reduce the volume of notifications made by industry, and the volume that EPA would need to process. Further, an active notification need only be made once per chemical to take effect, and it would be helpful if all stakeholders could view the status of such notifications in “real time” to assist their company-wide review processes.² It should be noted that this process would greatly reduce overall burden in cases where a manufacturer does not disclose chemical identity of composition to an importer; in such cases, the manufacturer could simply confirm to the importer that all components have already been notified as “active” (by anyone). This would avoid the need for protracted and complicated confidentiality agreements. If each manufacturer/importer must report individually and redundantly, each party would need to know complete compositions to do so.³

To Reduce Burden and Maximize the Efficiency and Timeliness of the Reset, CBI Substantiation Should be Addressed in a Separate, Subsequent Rulemaking Process.

The Reset serves two statutory functions. The first is to segregate the Inventory by active and inactive designations; this is a necessary prerequisite to inform prioritization under the Prioritization Rule, which applies to active chemicals on the Inventory. The second is to ensure that CBI claims for chemical identity on the Confidential Inventory have been systematically reasserted, substantiated, and reviewed.

EPA can complete the Reset most quickly and efficiently by segregating the CBI substantiation and review step in accordance with the review plan and longer timeline offered by the statute. The scale of effort, and burden, on both industry and the agency for both the Inventory Reset itself, as well as the CBI review, will be substantial, and attempting to conduct them simultaneously will grossly add to the overall burden and stress quality control systems. The Inventory Reset will require database and software management on the part of both industry and the agency, and should take into account the time needed to address software development or upgrade needs, system outages, and other issues that may arise. The new CBI obligations placed on the agency are also substantial, and there are separate obligations beyond the Inventory Reset itself that will require agency-wide management. For example, for claims that have already been

² The statute is quite clear that neither submissions nor reporting are required from industry. Any sort of scheme that required each individual company to notify against the full Inventory would not only result in an extraordinary burden on industry – it would overwhelm the agency with massive amounts of information, significant portions of which would be redundant. For example, for commodity chemicals, solvents, and catalysts, a company-specific notification process would result in EPA receiving hundreds or thousands of the same “active” notification for just a single chemical – a result then multiplied by thousands of chemicals.

³ Likewise, this approach would also reduce the burden on processors electing to participate.



fully substantiated in the CDR process for submissions made on or after June 22, 2016, no re-substantiation is now needed under the review plan for the Confidential Inventory. EPA would benefit greatly from fully utilizing the schedule set out by statute to ensure that the review plan does not require redundant re-substantiation and re-review for claims already addressed under the LCSA.

EPA Should Allow Manufacturers to List Chemical Equivalents with Active Chemical Notices.

Historical nomenclature conventions and registration practices have resulted in cases of the same chemical substance appearing multiple times on the Inventory under different names. At a minimum, it is important that the Reset process take this into account to ensure that the same substance not simultaneously be classified as both “active” and “inactive” following the Reset. EPA should therefore allow manufacturers to offer nomenclature equivalency notifications when active notifications are sought, which will allow EPA to make the necessary evaluation, in a timely manner, to avoid a dual active/inactive classification for the same chemical substance.

Processors Should Be Offered an Opportunity to Voluntarily Participate in the Reset.

Chemicals in commerce may include chemicals in stock but not currently manufactured or imported. Examples include substances produced or used infrequently or used for military purposes or resupply. Processors may be in the best position to identify, and offer notification, of such existing stock chemicals. The reset process would benefit from allowing processors the opportunity to participate without mandating that they do so.

EPA Should Consider A Simple, Rapidly Executed Procedure for Post-Reset Notifications Changing Inactive Status to Active.

After the 2017 Reset has been completed, EPA is required to update a substance's designation from inactive to active after a notice is received under Section 8(b)(5)(B)(iii). LCSA does not set forth any requirements for substantiation or data, either in the reset or thereafter, to make this notification. As with the Reset itself, LCSA describes the process as notification to the agency, not reporting. The process is also clearly described as a fairly automatic and prompt one; EPA must redesignate inactive substances to active “on receipt” of the notice.

We recommend that EPA clearly articulate the required elements for notice, but that these elements clearly reflect the purpose and intent of the statute for simplicity, ease of execution, and immediacy. Ideally, redesignation of a chemical from “inactive” to “active” would be self-executing upon the receipt of a statutorily compliant notice from a manufacturer. Indeed, Section (5)(B)(iii) suggests that this provision is intended to operate in an immediate and self-executing way; the statutory language requires EPA to designate a chemical as active “on,” not following, receipt of a notice. This makes good sense. There may be an immediate need to bring a particular chemical on the Inventory into production or use for a wide range of reasons – for example, a chemical may be immediately needed for a critical use like water purification – and even a short delay to redesignate a chemical from inactive to active could be untenable.



Thank you for your consideration. Please feel free to contact me at 202-249-6130 or Karyn_Schmidt@americanchemistry.com with any questions.

Sincerely,



Karyn M. Schmidt
Senior Director, Regulatory & Technical Affairs

cc: Wendy Cleland-Hamnett